INTRODUCTION

Proficiency testing (PT) providers assess laboratory performance by comparing a laboratory’s results with the assigned value and the acceptable range of performance, and assessments are based on total allowable error.

It is also possible to assess repeatability/precision by comparing results obtained in blind identical PT samples. Some PT providers provide an assessment of intra-laboratory precision by comparing results obtained in blind identical PT samples. A certain percentage of the results are flagged each time based on a pre-selected confidence level. The flagging rule is based on statistics and is not connected with the clinical use of the tests or performance expectations.

The aim of this study was to develop an assessment process that is based on clinical performance expectation. Comparing two test results from the same patient is a common practice in monitoring the change in the disease status. The reference change value (RCV) concept was introduced to assess if the difference between two consecutive test results for the same patient arises from assay imprecision and biological variation or from a real change that has occurred in the patient’s clinical status. The RCV concept is applied in IQMh PT schemes as a pilot to provide laboratories with additional information of repeatability or precision of their assay methods based on PT design.

METHODS AND MATERIALS

Blind identical samples were distributed to participants, and the per cent differences (D%) between the results obtained were calculated for the following analytes (precision goals are indicated in brackets): albumin (2.5%), bicarbonate (4%), calcium (2%), chloride (1.3 mmol/L [1.2%]), creatinine (3 μmol/L [3.6%]), glucose (2.5%), magnesium (2.5%), osmolality (1.7%), phosphate (2.5%), potassium (2%), protein-total (2%), sodium (1.3 mmol/L [0.9%]), iron (5%), total iron binding capacity (TIBC) (5%), transferrin saturation (7%), transferrin (4%), urea (0.3 mmol/L [8%]).

RCV is calculated using the formula $RCV = \sqrt{2} \times Z \times CV_T$, where $CV$ represents the precision targets determined by the scientific committee for PT purposes, and Z value of 1.96 for the 95% probability level, an acceptable RCV value was determined for each analyte and was called the flagging limit for PT purposes.

Then the per cent difference (D%) and the RCV was compared. Algorithm presented in Figure 1 was used for the determination of the PT actions. Participants have received PT reports demonstrated in Figures 2 and 3.

RESULTS

In the CHEM-1401 survey, a total of 19 out of 2671 results were flagged, since the per cent differences between blind identical samples, vials 1 and 2, were higher than the RCV (flagging limit). The precision proficiency testing pilot included 18 measurands. Flags were assigned to participants for bicarbonate, chloride, creatinine, magnesium, osmolality, protein-total, sodium, iron, TIBC, and transferrin saturation. This indicates that the change in analyte concentration is beyond the acceptable analytical CV, even though the two samples in the survey are identical. In 15 of these flagged per cent differences (79%), both results obtained in the blind identical samples were in the acceptable range when assessed against assigned value and total allowable error base acceptance criteria, PAD scores (Percent Allowable Difference = 100 * (Lab result – Assigned value)/Allowable Result Range Around Assigned Value); values between (−100) and (+100) are considered acceptable performance (Figure 3).

CONCLUSION

Results of the first pilot PT program indicate that incorporating assessment of repeatability in PT programs may facilitate identification of potential analytical errors, and can be used as a tool for root-cause analysis.